K033550

MAY - 5 2004

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5.0 510 (k) SUMMARY

Information shown in this section is furnished in accordance with 21CFR807.92. The paragraph headings correspond directly with those in 21CFR807.92.

807.92(a)(1) Name, address, telephone number, contact person and preparation date

- **Submitters name and address:**
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  Sweden

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- **Contact person**
  Joakim Arwidson
  International Product Manager
  Demetech AB
  Dalvägen 24
  169 56 Solna
  Sweden

- **Preparation date**
  November 7, 2003

807.92(a)(2) Proprietary/Trade name, Common name, Classification name

- **Proprietary/Trade name**
  DXL Calscan™

- **Common name**
  Bone Densitometer

- **Classification name**
  Bone Densitometer, 21CFR892.1170

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807.92(a)(3) Legally marketed device (predicate device)

- PIXI Bone Densitometer, GE Lunar, 510(k) K970224 & K983262
- DTX-200 Bone Densitometer, Osteometer Meditech, 510(k) K964562

807.92(a)(4) Description of the device that is subject of this premarket notification

The DXL Calscan™ Bone Densitometer estimates Bone Mineral Density (BMD) of the Os Calcis. The technology is based on Dual Energy X-ray Absorptiometry (DEXA). Heel width, measured by a laser ruler, enables patient-specific calculation for effects from soft and adipose tissues.

807.92(a)(5) Intended use

The DXL Calscan™ Bone Densitometer estimates bone mineral density (BMD) (g/cm^2) for the region of the heel (os calcis). By comparing estimated BMD to a physician-selected reference database, a T-score is calculated so that the physician, at his or her discretion, may assess fracture risk.

807.92(a)(6) Technological characteristics

One patient scan with DXL Calscan takes 55 seconds to perform. The effective patient dose is 0.02 mrem. Heel (os calcis) width is measured by laser ruler with a maximum power of 5 mW and wavelength 635 nm.

807.92(b)(1) Brief discussion of the nonclinical tests submitted, referenced or relied on in this premarket notification submission.

DXL Calscan in vitro Accuracy Study shows correlation (r=0.99) between estimated BMD and actual hydroxyapatite content.

DXL Calscan in vitro Short-Term Precision Study shows BMD precision error (CV%) of 0.77%.

DXL Calscan in vitro Laser Ruler Study shows short-term precision error (CV%) of 0.01% and an accuracy error of 1.5%.

807.92(b)(2) Brief discussion of the clinical tests submitted, referenced or relied on in this premarket notification submission.

DXL Calscan in vivo Short-Term Precision Study shows BMD precision error (CV%) of 1.2%.

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807.92(b)(3) Conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well or better than the predicate device.

Based on the results from the tests, the DXL Calscan™ Bone Densitometer is substantially equivalent to previously registered devices. No new safety and effectiveness questions are raised with the DXL Calscan Bone Densitometer.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Mr. Joakim Arwidson
International Product Manager
DEMETECH AB
Box 3095
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SWEDEN

Re: K033550
Trade/Device Name: DXL Calscan
Bone Densitometer
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: 90 KGI
Dated: March 14, 2004
Received: March 16, 2004

Dear Mr. Arwidson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

8.0 INDICATION FOR USE FORM

- 510(k) Number (if known) _033550_
- Device Name: DXL Calscan
- Indications for use:

The DXL Calscan™ Bone Densitometer estimated bone mineral density (BMD) (g/cm^2) for the region of the heel (os calcis). By comparing estimated BMD to a young Caucasian female database, a T-score is calculated so that the physician, at his or her discretion, may assess fracture risk.

One patient scan with DXL Calscan takes 55 seconds to perform. The effective patient dose is 0.02 mrem. This performance is substantially equivalent to PIXI performance and poses no new safety or efficacy concerns.

Use of the DXL Calscan is restricted to prescription use only. The Operator's Manual for the DXL Calscan contains the following statement:

> "United States Federal Law restricts this device to the sale, distribution and use by or on the order of a physician."

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___✓___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033550